

**Title: *CareStart*<sup>TM</sup> COVID-19 ANTIGEN TEST SHELF-LIFE EXTENSION NOTIFICATION**

Date: July 19, 2021

To Whom It May Concern,

This letter is to inform you regarding the extension of the shelf-life expiration date of the Access Bio, Inc. *CareStart*<sup>TM</sup> COVID-19 ANTIGEN test. As a part of the EUA requirement, the US Food and Drug Administration (FDA) requested Access Bio, Inc. to indicate shelf life of the product based on the real-time stability data.


To comply with the requirement, Access Bio, Inc. submitted the real-time stability data on July 15<sup>th</sup>, 2021, and the FDA granted **twelve (12) months of shelf-life at 1–30°C for the *CareStart*<sup>TM</sup> COVID-19 ANTIGEN test as of July 16<sup>th</sup>, 2021.**

**Attachment A** lists the lot numbers of *CareStart*<sup>TM</sup> COVID-19 ANTIGEN products labeled with six (6). These products' shelf-life will now be extended to twelve (12) months.

Name: Seungjae Baek

Job Title: Sr. Managing Director, Quality Management

Signature:



### Attachment A

List of Lot Numbers printed with 6 months shelf life and new extended shelf life

Lot Numbers	Printed Shelf Life (6 Months)	Extended Shelf Life (12 Months)
CH20J06, CH20J07	FEB 2021	AUG 2021
CH20K01, CH20K02, CH20K03, CH20K04	MAR 2021	SEP 2021
CH20L01, CH20L02, CH20L03, CH20L04, CH20L05, CH20L06, CH20L07, CH20L08, CH20L09	APR 2021	OCT 2021
CH20M01, CH20M02, CH20M03, CH20M04, CH20M05, CH20M06, CH20M07, CH20M08, CH20M09, CH20M10, CH20M10-1, CH20M12, CH20M13, CH20M14, CH20M15, CH20M16, CH20M17, CH20M18, CH20M19, CH20M20, CH20M21, CH20M22, CH20M23	MAY 2021	NOV 2021
CH21A01, CH21A02, CH21A03, CH21A04, CH21A05, CH21A06, CH21A07, CH21A08, CH21A09, CH21A10, CH21A11, CH21A12, CH21A13, CH21A14, CH21A15, CH21A16, CH21A17, CH21A18, CH21A19, CH21A20, CH21A21, CH21A21-1, CH21A22, CH21A23, CH21A24, CH21A25, CH21A26, CH21A27, CH21A28 CH21A29, CH21A30	JUN 2021	DEC 2021
CH21B01, CH21B02, CH21B03, CH21B04, CH21B05, CH21B06, CH21B07, CH21B08, CH21B09, CH21B10, CH21B11, CH21B12, CH21B13, CH21B14, CH21B15, CH21B16, CH21B17, CH21B18, CH21B19, CH21B20, CH21B21, CH21B22, CH21B23, CH21B24	JUL 2021	JAN 2022